REMARKS

Interview summary

Undersigned counsel for Applicant wishes to sincerely thank the Examiner for the courtesy of a personal interview held at the USPTO on November 11, 2008. During the Interview, Applicant explained, first, that the present invention is directed to a pharmaceutical composition that is retained in the mouth so that it may release an active agent into the mouth, whereas prior art "sustained release" compositions have released the active agent to the stomach and intestines in a "sustained" manner, which can retard or abrogate systemic uptake of the agent. Second, to the extent the Examiner has cited art that teach delivery of drugs to the mouth, Applicant explained that those disclosures are silent on the administration of an agent "that is not absorbed through the oral mucosa to a substantial extent." In fact, those references teach away from the inventive compositions.

The Examiner appeared to express some concern over "inherent" delivery, if any, of some active agent into the stomach from medicaments designed for buccal delivery. Applicant suggested that even if it is assumed that some drug could have unintentionally entered the stomach, one of ordinary skill in the art would not have considered such an amount "substantial," as currently claimed. Furthermore, with this paper, Applicant has amended the claimed compositions to recite a "holding device." Hence, even assuming, *arguendo*, the prior art composition were intended for a *user* to retain a medicament in the mouth, no reference uncovered by the Examiner thus far teaches *compositions* as claimed further comprising a holding device.

Status of the claims

Claims 1-5 and 7-15 were pending in the subject application, of which claims 8-13 had been withdrawn from consideration by the Examiner. With this submission, claims 1, 4 and 14 have been amended; claim 5 has been canceled; and claims 17 and 18 have been newly added.

Hence, upon entry of this paper, claims 1-4 and 7-18 will be pending in the subject application, with claims 8-13 withdrawn from consideration by the Examiner.

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim amendments

Claim 1 has been amended to incorporate that language of original claim 5 and can thus find support therefrom. Support for "plastic holder" as recited in claim 4 can be found in paragraph 30 of the original application. Support for claim 17 may be found at least in paragraph 29 of the as-filed application; and support for claim 18 may be found at least in paragraph 20 of the same disclosure. Hence, Applicant respectfully submits that no new matter has been introduced with these amendments.

Claim rejections under 35 U.S.C. § 102

Claims 1-3, 5, 7 and 14 remain rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 6,004,582 to Faour *et al.* ("Faour"); claims 1, 2, 4, 5, 7, 14 and 15 remain rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. 6,197,331 to Lerner *et al.* ("Lerner"); and claims 1, 2, 5-7 and 14 remain rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. 3,065,143 to Christenson *et al.* ("Christenson"). Reasons for the rejections are of record and therefore not reiterated herein. Applicant kindly traverses the rejections.

In the last-filed Response, Applicant rebutted the Examiner's allegations of anticipation, noting, in part, that none of the references taught pharmaceutical compositions that *released* an active agent in the oral cavity for substantial *absorption* in the gastrointestinal tract. Faour, it was noted, teaches an osmotic device that delivers the active agent(s) to "benefit the environment of use," including sublingual and buccal environments (Col. 4, l. 4-18 and 35-42). Lerner states that his compositions are designed to deliver a pharmaceutical agent for "local" treatment of the oral cavity, throat or esophagus; to provide a composition for "topical release to sites of

attachment"; and to provide a composition for oral release of a pharmaceutical, allowing for "*buccal absorption.*" *See, e.g.*, col. 6, l. 64-67 and col. 7, l. 1-4. Finally, Christenson teaches the use of a "traditional" pharmaceutical tablet, one that is ingested *and* consumed via the gastrointestinal tract. (Col. 1, l. 8-11, disclosing "medicinal agents for oral administration in the form of the tablets which provide a substantially constant rate of release of the medicament *in the gastro-intestinal tract.*")

The Examiner appears to appreciate the nature of the present invention, however, as noted in the Interview Summary, the Examiner seems concerned over "inherent" delivery, if any, of some active agent into the stomach from medicaments designed for buccal delivery (*e.g.*, Faour, Lerner). The Examiner has also expressed the possibility that compositions clearly not intended for oral retention, may nonetheless be actively retained by the user (*e.g.*, Christenson).

At the outset, Applicant kindly notes that a proper rejection for anticipated can only be maintained if each and every limitation of the claimed invention is expressly or inherently taught in a single reference. Faour and Christenson are silent with respect to a "holding device." With respect to any "inherent" disclosure of same, Applicant respectfully suggests that a *user's* tongue cannot suffice as the claimed *composition's* "holding device." This is so because, even assuming, *arguendo*, a prior art composition intended for swallowing was deliberately retained in the mouth by a *user* (presumably contradicting the directions for its administration), that composition *per se* would still lack a "holding device" as required of the claims.

With respect to the Examiner's suggestion that the active agent of some prior art compositions designed for oral delivery may have been "inherently" swallowed thereby reading on "systemic absorption in the gastrointestinal tract," Applicant respectfully submits that, even if so, one of ordinary skill in the art would not have considered such an amount "substantial." Merriam-Webster provides the following definitions for "substantial": "not imaginary or illusory," "essential," "considerable in quantity," and "significantly great."[1] Viewed in this light,

[1] Merriam-Webster's Collegiate Dictionary 1245 (11th ed. 2003).

no ordinary artisan would reasonably conclude that any unintentional run off of medication intended for oral absorption into the stomach as "substantial." Furthermore, in any event, there is no evidence that such ingestion would lead to "an absorption window of less than 6 hours."

Taken together, Applicant respectfully submits that the claimed invention cannot be anticipated by the cited references. Hence, Applicant respectfully requests the withdrawal of same.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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